

DARPA-BAA-11-73

Frequently Asked Questions

Last Updated: October 7, 2011

GENERAL INFORMATION

Q: What DARPA seedlings predate this program? Are reports available?

A: There was an informational workshop hosted by DARPA and the U.S. Food and Drug Administration (FDA) in June of 2011. Presentations and Breakout Session Transcripts from this workshop can be found at the teaming website: <https://team.sainc.com/MPSys>.

PROPOSALS

Q: Can a prime or collaborator be an international company?

A: Yes, international companies and universities are acceptable.

Q: Is subcontracting to a National Lab or Federally Funded Research and Development Center (FFRDC) permitted?

A: Yes. Proposer should comply with the section on FFRDCs as stated within the BAA.

Q: Will any response be provided to abstracts?

A: It is anticipated that replies will be made on whether proposals are encouraged or discouraged.

COST

Q: What is the overall DARPA budget for the Microphysiological Systems program? Are there funding limits for individual proposals?

A: The investment profile for the Microphysiological Systems program has not been fixed at this time. The final program will depend on the proposals selected for funding. At this time, no single-project funding limits have been set.

Q: What is meant by Calendar Fiscal Year?

A: Calendar Fiscal Year = Jan – Dec.

Q: Would a Firm Fixed Price proposal with milestone payments be acceptable?

A: A firm fixed price contract is possible. It would depend on the quality of the proposal and the specific facts related to the cost elements.

PROGRAM STRUCTURE

Q: How many awards are anticipated?

A: The number of awards will depend on the merits of the proposals received and funds available.

Q: Does the proposal have to follow exactly the program outline specified in the BAA?

A: Proposers should adhere closely to the objectives described in the BAA. Work distributed among the phases may be reorganized as long as it is in keeping with the overall technical objectives and the program progress.

Q: If one of the stated goals does not make sense given a chosen approach, can I propose a complementary milestone?

A: Yes. You are welcome to propose different or additional milestones, but you must be able to justify within your proposal that what you are bidding for that goal is consistent with the stated program goals and will not produce unmanageable additional technical risk.

Q: Is DARPA-BAA-11-73 the joint project with NIH and FDA that is referred to by Chemical and Engineering News (among other publications), which will "develop a chip to quickly screen drugs for toxicity and effectiveness"?

A: The short answer is yes, numerous web postings and press releases do in fact refer to DARPA-BAA-11-73 (Microphysiological Systems). The long answer is that the Microphysiological Systems program is an entirely DARPA-funded and -managed program. The FDA and NIH will be providing technical expertise and guidance throughout the program so that the final product provides the greatest value to the scientific community. As other government agencies develop and fund complementary programs of their own, these will be coordinated with the DARPA effort.

TEAMING

Q: Should the research team reflect the desired components, particularly if experts in each of the 10 defined biological systems are assembled? While this approach would seem to be the most reasonable, it would lead to a team of 15+ investigators and thus a very significant annual budget.

A: The BAA describes four technical areas that must be addressed by the proposing team (plus one optional technical area). It is up to the proposers to form a team that is likely to accomplish the goals of the Program. The BAA also states that "proposals from teams with personnel and/or entities with a demonstrated track record of commercializing or transitioning products are preferred."

Q: Would a project proposal involving co-Principal Investigators be eligible under this BAA, or is a single Principal Investigator structure the only eligible option, as far as an organizational structure?

A: Co-PIs are permitted. However, a lead/prime organization must be identified, for contractual/funding purposes.

TECHNICAL

Q: Is my topic consistent with the objectives of the BAA?

A: DARPA is not able to suggest specific research approaches. If you feel that your chosen effort is consistent with the objectives of the BAA and capable of meeting the goals stated within the BAA, then you should feel free to propose them. It is strongly encouraged that you read the BAA carefully. It is your burden to make clear within your proposal that your approach is supportive of your innovative claims, and includes a detailed analysis of the technical motivation.

Q: Does this proposal require 3-dimensional tissue construct? Can it be 2-dimensional between scaffold and cell?

A: There is no requirement for 3-dimensional tissue constructs. It is up to the proposers to utilize an architecture that demonstrates authentic tissue and cell responses.

Q: The solicitation says that the systems have to be reliable and user-friendly. Would the assays systems be eventually adopted by the military and performed by scientific personnel in a GLP environment?

A: The intent of this program is to develop a platform that is suited to the academic or industry research laboratory.

Q: Is there is an interest in the development of 3-dimensional heart tissue using stem cells for studying bioterrorism countermeasures for this program?

A: As described in the BAA, proposals must address all four technical areas (plus one that is optional). Proposals that do not address the four required areas will not be evaluated.

Q: Can you elaborate on the text taken from the solicitation? “Platforms must also be designed, built, and demonstrate sufficient functional or reserve capacity such that the total tissue sustained by the end of the Base period (and each additional Period) is equivalent to the full complement of ten physiological systems expected at the end of the program. Depending on the number of different physiological systems available at the time (see Milestones below), multiple copies of one or more systems should be used so that ten systems are sustained by the platform at the end of each funding period.”

A: At the end of the base period, the platform must sustain two physiological systems. As per the program milestones, performers are required to gradually increase the number of systems that are resident on their platform. Consider what would happen if, at the end of the first optional period, you discover that the platform cannot sustain the two additional systems (total 4) you need to meet the program milestone, perhaps because there was insufficient supply of nutrients. In that case, you might need a major redesign of the platform. Instead, we ask that you demonstrate that the platform can sustain ten systems at the end of the base period so that future major redesigns are avoided. Of course, at the

end of the base period you will only have developed two physiological systems, so you'll need to put 5 copies of each on the platform to show that the platform can sustain (5 x 2 =) ten physiological systems.

Q: The BAA states “All of the following physiological systems must be functionally represented on the platform by the end of the program: circulatory, endocrine, gastrointestinal, immune, integumentary, musculoskeletal, nervous, reproductive, respiratory, and urinary.” Does this mean that a responsive platform needs to represent all of these systems or that it can focus on one or two?

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